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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/659,801 | 09/10/2003 | Susan Chubinskaya | PU3680US3 | 5240 |

23347 7590 05/23/2006

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| EXAMINER | |
|---|---|
| WANG, SHENGJUN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1617 | |

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/659,801 | CHUBINSKAYA ET AL. | |
| | Examiner | Art Unit | |
| | Shengjun Wang | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5 and 7-27* is/are pending in the application.

4a) Of the above claim(s) *8,15,16 and 18-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,9-14,17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Receipt of applicants' amendments and remarks submitted February 16, 2006 is acknowledged.

### *Claim Rejections 35 U.S.C. § 103*

a. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-5, 7, 9-14, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann et al. (Journal of Biological Chemistry, 273(5), 2885-94) in view of Miao et al. (USPN 6093723). Hofmann et al. teaches BDA452 as an inhibitor of the calcium influx activity of annexin V (a binder of callogen II) (p. 2891-2). Hofmann et al. does not teach the treatment of arthritis with the claimed compounds.

Miao et al. teaches that agents that inhibit calcium influx are useful in the treatment of autoimmune diseases, inflammatory diseases, rheumatoid arthritis, etc. (col. 1, lines 10-44; col. 12, lines 35-59).

It would have been obvious to one of ordinary skill in the art at the time of the invention to treat arthritic conditions with the compound as instantly claimed because (1) Hofmann et al. teaches the compound as a known inhibitor of calcium influx; and (2) Miao et al. teaches calcium influx inhibitors as known for the treatment of inflammatory disorders, rheumatoid arthritis, etc. One would have been motivated to utilize the benzodiazepines of Hofmann et al.

because of an expectation of success in treating arthritic conditions with an agent known to possess functional capabilities known in the art to be useful therefor.

***Response to the Arguments***

Applicants' amendments and remarks submitted February 16, 2006 have been fully considered. The amendments and remarks are persuasive to overcome the rejections under 35 U.S.C. 112, but are unpersuasive as to the rejections set forth above.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teachings, suggestions, and motivations are found in the cited references and in the knowledge generally available to one of ordinary skill in the art. Particularly, Miao teaches that agents that inhibit calcium influx are useful in the treatment of autoimmune diseases, inflammatory diseases, rheumatoid arthritis, etc. Hofmann et al. teaches that the compound employed herein, BDA452, as an inhibitor of the calcium influx activity of annexin V. Therefore, it would have been obvious to use an inhibitor of the calcium influx activity to treat a disorder that is treatable by such inhibitor. The employment of BDA452 is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2nd 1387 (at 1388).

3. Applicants contend that the compounds exemplified in Miao et al. and BDA452 are "wholly unrelated" and there is no teaching or suggestion that "structurally unrelated compounds having one property in common would therefore have more or all properties in common." The examiner notes that the "one property in common" provides sufficient teaching, suggestions and motivation to reach the claimed invention. The instant claims are directed to affecting a biochemical pathway with an old and well known compounds. The argument that such claims are not directed to the old and well known ultimate utility (inhibiting calcium influx activity and thereby treating arthritis) for the compounds, BDA452, are not probative. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617